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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,587	12/04/2001	Michael A. Tainsky	0788.00063	5172

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,587	TAINSKY ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 10 drawn to a diagnostic tool and a kit for use in diagnosing a disease, classified in class 422, subclass 50.

II. Claims 5-6, drawn to a combination of markers for diseases, classified in class 435, subclass 174.

III. Claims 7-9, drawn to a method of detecting a combination of markers, classified in class 435, subclass 6.

IV. Claim 11, drawn to epitopes, classified in class 424, subclass 130.1.

V. Claim 12, drawn to a method of detecting disease, classified in class 435, subclass 7.1.

VI. Claim 13, drawn to a database, classified in class 702, subclass 19.

VII. Claim 14, drawn to a method of selecting indicative epitopes, classified in class 435, subclass 7.1.

VIII. Claim 15, drawn to a method for processing data, classified in class 707, subclass 101.

IX. Claim 16, drawn to a tool for interpreting results of disease screening, classified in class 702, subclass 19.

X. Claim 17-18, drawn to a method of creating an array of markers, classified in class 435, subclass 6.

XI. Claim 19, drawn to a biochip for detecting presence of disease markers, classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, V, VII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are as follows:

Group I and Group II are unrelated in that Group I is directed to a tool and kit for use in diagnosis and Group II is directed to a combination of markers. Each represents a different product, which are unrelated.

Group I and Group III are unrelated in that Group I is directed to tool and a kit for diagnosis and Group III is directed to method of detection, not encompassing the same limitations therein.

Group I and Group IV are unrelated in that Group I is directed to a tool and a kit for diagnosis with a detection means and Group IV is directed to eptitopes not included in the limitations of Group I.

Group I and Group V are unrelated in that Group I is directed to a tool and kit for diagnosis and Group V is directed to a method of detection of disease by antibody analysis. Group V detection does not require the use of the Group I tool and encompasses different claim limitations.

Group I and Group VI are unrelated in that Group I is directed to a tool for diagnosis and Group VI is directed to a database of epitopes. The claims have different limitations and do not encompass the same inventive purpose.

Group I and Group VII are unrelated in that Group I is directed to a tool for diagnosis and Group VII is directed to a method of selecting epitopes, which includes a different inventive purpose and different claim limitations.

Group I and Group VIII are unrelated in that Group I is directed to a tool for diagnosis and Group VIII is directed to a method of processing data by normalization. The claims are directed to different subject matter and have different outcomes.

Group I and Group IX are unrelated in that Group 1 is directed to a tool for diagnosis and Group IX is directed to a tool for interpreting results. The claims are directed to different subject matter and contain different limitations.

Group I and Group X are unrelated in that Group I is directed to a toll for diagnosis and Group XI is directed to a method of creating an array. The claims are directed to different subject matter.

Groups I and Groups XI are unrelated in that Group I is directed to a tool for diagnosis and Group XI is directed to a biochip. The tool of Group I is no limited to be a biochip and could also include other arrays, such as a 96-well plate array.

Claims II and V are unrelated in that Group II is directed to a combination of markers for diseases and Group V is directed to a method of detecting disease using antibodies. The limitations of Group V do not require the markers of Group II.

Claims II and VI are unrelated in that Group II is directed to a combination of markers and Group VI is directed to a database that does not contain the markers of Group II.

Claims II and VII are unrelated in that Group II is directed to a combination of markers and Group VII is directed to selecting epitopes that are not the same as the markers of Group II.

Group II and Group VIII are unrelated in that Group II is directed to a combination of markers and Group VIII is directed to a method of processing data by normalization, which is a completely different subject are from that of biological markers of Group II.

Group II and Group IX are unrelated in that Group II is directed to a combination of markers and Group IX is directed to a tool comprising a computer for interpreting results of disease screening, which does not require the marker set of Group II.

Group II and Group X are unrelated in that Group II is directed to a combination of markers and Group X is directed to a method of creating an array of markers that is not limited to those markers set forth in Group II.

Group II and Group XI are unrelated in that Group II is directed to a combination of markers and Group XI is directed to a biochip for detecting markers, not limited to those of Group II.

Group III and Group VII are unrelated as Group III is directed to a method of detecting markers of disease and Group VII is directed to a method of selecting indicative epitopes. Both Groups include vastly different steps and have different inventive outcomes.

Group III and Group VIII are unrelated in that Group III is directed to a method of detecting markers of disease and Group VIII is directed to a method of processing data which is a completely different subject are from that of biological methods of Group III.

Group III and Group IX are unrelated as Group III is directed to a method of detecting markers of disease and Group IX is directed to a tool for interpreting results of disease screening. The method of detecting does not require the tool of Group IX.

Group III and Group X are unrelated in that Group III is directed to a method of detecting markers of disease and Group X is directed to a method of creating an array. Both Groups require different inventive steps and lead to different outcomes.

Group III and Group XI are unrelated in that Group III is directed to a method of detecting markers of disease, which does not require the biochip of Group XI.

Groups IV and Group V are unrelated in that Group IV is directed to eptiopes and Group V is directed to a method of detecting disease, which is not limited using the epitopes of Group IV.

Group IV and Group VII are unrelated in that Group IV is directed to eptiopes and Group VII is directed to a method of selecting epitopes, which are not limited to be the epitopes of Group IV.

Group IV and Group VIII are unrelated in that Group IV is directed to eptiopes and Group VIII is directed to a method of processing data which is a completely different subject area from that of biological methods of Group IV.

Group IV and Group IX are unrelated in that Group IV is directed to eptiopes and Group IX is directed to a tool for interpreting results of disease screening, which does not require the epitopes of Group IV.

Group IV and Group X are unrelated in that Group IV is directed to epitopes and Group X is directed to a method of creating an array, which does not require the use of the epitopes of Group IV.

Group IV and Group XI are unrelated in that Group IV is directed to eptiopes and Group XI is directed to a biochip, which does not require the epitopes of Group IV.

Group V and Group VI are unrelated in that Group V is directed to a method of detecting disease and Group VI is directed to a database comprising epitopes. The methods of detecting disease are not related in subject matter to the database that contains epitopes. The methods do not require the database.

Group V and Group VII are unrelated in that Group V is directed to a method of detecting disease and VII is directed to a method of selecting epitopes, which are not required in the method of Group V.

Group V and Group VIII are unrelated in that Group V is directed to a method of detecting disease and Group VIII is directed to a method of processing data which is a completely different subject area from that of biological methods of Group V.

Group V and Group IX are unrelated in that Group V is directed to a method of detecting disease and Group IX is directed to a tool for interpreting results of disease screening, not required for use in the method of Group V.

Group V and Group X are unrelated in that Group V is directed to a method of detecting disease and Group X is directed to a method of creating an array. Both require different method steps and lead to different inventive outcomes.

Group V and Group XI are unrelated in that Group V is directed to a method of detecting disease and XI is directed to a biochip, which is not required in the method of Group V.

Group VI and Group VII are unrelated in that Group VI is directed to a database comprising epitopes and Group VII is directed to a method of selecting epitopes. The database of Group VI is not included in the selection process of Group VII.

Group VI and Group VIII are unrelated in that Group VI is directed to a database comprising epitopes and Group VIII is directed to a method of processing data which is a completely different subject area from that of biological database of Group VI.

Group VI and Group IX are unrelated in that Group VI is directed to a database comprising epitopes and Group IX is directed to a tool for interpreting results of disease screening which does not employ the database of Group VI.

Group VI and Group X are unrelated in that Group VI is directed to a database comprising epitopes and Group X is directed to a method of creating an array, which does not use the database of Group VI.

Group VI and Group XI are unrelated in that Group VI is directed to a database comprising epitopes and XI is directed to a biochip. Both are different products with different inventive purposes.

Group VII and Group VIII are unrelated in that Group VII is directed to a method of selecting indicative epitopes and Group VIII is directed to a method of processing data which is a completely different subject area from that of biological method of Group VII.

Group VII and Group IX are unrelated in that Group VII is directed to a method of selecting indicative epitopes and Group IX is directed to a tool for interpreting results of disease screening. The method of Group VII does not require the use of the tool in Group IX.

Group VII and Group X are unrelated in that Group VII is directed to a method of selecting indicative epitopes and Group X is directed to a method of creating an array, which is directed to a different inventive purpose and outcome from the selection of epitopes in Group VII.

Group VII and Group XI are unrelated in that Group VII is directed to a method of selecting indicative epitopes and Group XI is directed to a biochip. The biochip of Group XI is not required in the method for selecting epitopes of Group VII.

Group VIII and Group IX are unrelated in that Group VIII is directed to a method of processing data and Group IX is directed to a tool for interpreting results of disease screening. The method of processing data by normalization has different inventive steps and outcomes from the method of Group IX.

Group VIII and Group X are unrelated in that Group VIII is directed to a method of processing data and Group X is directed to a method of creating an array. The method of processing data by normalization has different inventive steps and outcomes from the method of Group X.

Group VIII and Group XI are unrelated in that Group VIII is directed to a method of processing data and Group XI is directed to a biochip. The method of Group VIII does not require the biochip of Group XI.

Group IX and Group X are unrelated in that Group IX is directed to a tool for interpreting results of disease screening and Group X is directed to a method of creating an array, which does not require the tool of Group IX.

Group IX and Group XI are unrelated in that Group IX is directed to a tool for interpreting results of disease screening and Group XI is directed to a biochip. The products are different and have different inventive steps. Group IX includes a computer, not present in the invention of Group XI.

Group X and Group XI are unrelated in that Group X is directed to a method for creating an array and Group XI is directed to a biochip, which is not used in the method of Group X.

The inventions of Groups II and III are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the markers of Group II can be used in the distinct processes of the invention of Group III. However, the method of Group III may also be used for detection of disease states that do not include the markers of Group II or for the detection of polymorphisms in a patient.

The inventions of Group IV and Group VI are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the epitopes of Group IV can be used in the distinct processes (the database) of the invention of Groups VI, but may also be used for immunoassay, as in ELISA detection.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (571) 272-0549.

March 22, 2004
Lori A. Clow, Ph.D.
Lori A. Clow

MPW

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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3.22.04